



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Fallaux et al.

**Serial No.:** 10/618,526

**Filed:** July 11, 2003

**For:** PACKAGING SYSTEMS FOR  
HUMAN RECOMBINANT ADENOVIRUS  
TO BE USED IN GENE THERAPY

**Confirmation No.:** 5055

**Examiner:** D. Nguyen

**Group Art Unit:** 1632

**Attorney Docket No.:** 2578-3833.9US

**NOTICE OF EXPRESS MAILING**

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Person making Deposit: Steve Wong

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

Other Documents

WHITE et al., Adenovirus E1B 19-Kilodalton Protein Overcomes the Cytotoxicity of E1A Proteins, *Journal of Virology*, June 1991, pp. 2968-78, Vol. 65, No. 6.

WHITE et al., Role of Adenovirus E1B Proteins in Transformation: Altered Organization of Intermediate Filaments in Transformed Cells That Express the 19-Kilodalton Protein, *Molecular and Cellular Biology*, Jan. 1990, pp. 120-30, Vol. 10, No. 1.

GenBank Accession No. X02996.1, 1993, "Adenovirus type 5 left 32% of the genome."

WHITE et al., Specific disruption of intermediate filaments and the nuclear lamina by the 19-kDa product of the adenovirus E1B oncogene, *Proc. Natl. Acad. Sci.*, December 1989, pp. 9886-90, Vol. 86.

GALLIMORE et al., Transformation of Human Embryo Retinoblasts with Simian Virus 40, *Adenovirus and ras Oncogenes*, *Anticancer Research*, 1986, pp. 499-508, Vol. 6.

HITT et al., Construction and Propagation of Human Adenovirus Vectors, *Cell Biology*, 1994, pp. 479-90, Vol. 1, Academic Press, San Diego, California.

MITANI et al., Rescue, propagation, and partial purification of a helper virus-dependent adenovirus vector, *Proc. Natl. Acad. Sci.*, April 1995, pp. 3854-58, Vol. 92.

MARCK, CHRISTIAN, 'DNA Strider': a 'C' program for the fast analysis of DNA and protein sequences on the Apple Macintosh family of computers, *Nucleic Acids Research*, 1988, pp. 1829-36, Vol. 16, No. 5.

PESHWA et al., Cultivation of Mammalian Cells as Aggregates in Bioreactors: Effect of Calcium Concentration on Spatial Distribution of Viability, 1993, pp. 179-87, Vol. 41.

BERG et al., High-Level Expression of Secreted Proteins from Cells Adapted to Serum-Free Suspension Culture, *BioTechniques*, 1993, pp. 972-78, Vol. 14, No. 6.

WHITE et al., The 19-Kilodalton Adenovirus E1B Transforming Protein Inhibits Programmed Cell Death and Prevents Cytolysis by Tumor Necrosis Factor alpha, *Molecular and Cellular Biology*, June 1992, pp. 2570-80, Vol. 12, No. 6.

COLBY et al., Adenovirus Type 5 Virions Can Be Assembled In Vivo in the Absence of Detectable Polypeptide IX, *Journal of Virology*, Sept. 1981, pp. 997-80, Vol. 39, No. 3.

RULEY, H. EARL, Adenovirus early region 1A enables viral and cellular transforming genes to transform primary cells in culture, *Nature*, August 1983, pp. 602-06, Vol. 304.

GRAHAM et al., Size and location of the transforming region in human adenovirus type 5 DNA, *Nature*, October 25, 1974, pp. 687-91, Vol. 251.

PRELICH et al., Functional Characterization of Thermolabile DNA-Binding Proteins That Affect Adenovirus DNA Replication, *Journal of Virology*, Mar. 1986, pp. 883-92, Vol. 57, No. 3.

WOODWORTH et al., Transformation of Differentiated Rat Hepatocytes with Adenovirus and Adenovirus DNA, *Journal of Virology*, Nov. 1987, pp. 3570-79, Vol. 61, No. 11.

RAO et al., The adenovirus E1A proteins induce apoptosis, which is inhibited by the E1B 19-kDa and Bcl-2 proteins, *Proc. Natl. Acad. Sci.*, August 1992, pp. 7742-46, Vol. 89.

ROWE et al., Establishment and Characterization of Hamster Cell Lines Transformed by Restriction Endonuclease Fragments of Adenovirus 5, *Journal of Virology*, Jan. 1984, pp. 162-70, Vol. 49, No. 1.

SAMBROOK et al., Molecular Cloning -- A Laboratory Manual, 3rd edition, 2001, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York.

ACSADI et al., Adenovirus-mediated gene transfer into striated muscles, *J Mol Med*, 1995, pp. 165-80, Vol. 73.

NCBI database excerpt: Locus AC\_000008 (human adenovirus type 5)

RHIM, JOHNG S., Development of Human Cell Lines from Multiple Organs, 2000, *Annals New York Academy of Sciences*, pp. 16-25.

Notice of Opposition to a European Patent by Serono International S.A. filed against Patent No. 0 833 934 (July 5, 2005).

Opposition lodged by Cevec Pharmaceuticals GmbH against European Patent 0 833 934 (July 5, 2005).

Although this Supplemental Information Disclosure Statement is filed after the issuance of a final office action, pursuant to 37 C.F.R. § 1.97(d), the undersigned submits that, to the best of his information and belief, "that each item of information contained in the [supplemental] information disclosure statement was first cited [a] communication (*i.e.*, transmittals of notices of opposition) from a foreign patent office (*i.e.*, the European Patent Office) in a counterpart foreign application not more than three months prior to the filing of the [supplemental] information disclosure statement". 37 C.F.R. § 1.97(e)(1). The fee set forth in 37 C.F.R. § 1.17(p) accompanies this Supplemental Information Disclosure Statement.

Respectfully submitted,



Allen C. Turner  
Registration No. 33,041  
Attorney for Applicants  
TRASKBRITT, P.C.  
P.O. Box 2550  
Salt Lake City, Utah 84110-2550  
Telephone: 801-532-1922

Date: August 5, 2005

ACT/bv

Enclosures: Form PTO/SB/08  
Copy of documents cited

Document in ProLaw



Substitute for form 1449A/PTO		<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application Number	10/618,526
<i>(use as many sheets as necessary)</i>		Filing Date	July 11, 2003
Sheet	1	of	2
		First Named Inventor	Fallaux et al.
		Group Art Unit	1632
		Examiner Name	D. Nguyen
		Attorney Docket Number	2578-3833.9US

<b>NON PATENT LITERATURE DOCUMENTS</b>				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
		WHITE et al., Adenovirus E1B 19-Kilodalton Protein Overcomes the Cytotoxicity of E1A Proteins, <i>Journal of Virology</i> , June 1991, pp. 2968-78, Vol. 65, No. 6.		
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		GALLIMORE et al., Transformation of Human Embryo Retinoblasts with Simian Virus 40, Adenovirus and ras Oncogenes, <i>Anticancer Research</i> , 1986, pp. 499-508, Vol. 6.		
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		MARCK, CHRISTIAN, 'DNA Strider': a 'C' program for the fast analysis of DNA and protein sequences on the Apple Macintosh family of computers, <i>Nucleic Acids Research</i> , 1988, pp. 1829-36, Vol. 16, No. 5.		
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Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Sheet

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Examiner Name	D. Nguyen

Attorney Docket Number 2578-3833 9JUS

## NON PATENT LITERATURE DOCUMENTS

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		RULEY, H. EARL, Adenovirus early region 1A enables viral and cellular transforming genes to transform primary cells in culture, Nature, August 1983, pp. 602-06, Vol. 304.	
		GRAHAM et al., Size and location of the transforming region in human adenovirus type 5 DNA, Nature, October 25, 1974, pp. 687-91, Vol. 251.	
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